DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 2, 2015

Intuitive Surgical Incorporated
Ms. Nadine Nasr
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K143132
Trade/Device Name: IS4000 8mm Harmonic ACE™ Curved Shears
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: February 23, 2015
Received: February 25, 2015

Dear Ms. Nasr,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143132

Device Name
IS4000 8mm Harmonic ACE™ Curved Shears

Indications for Use *(Describe)*
The IS4000 Harmonic ACE™ Curved Shears is intended for soft tissue incisions when bleeding control and minimal thermal injury are desired. It is designed to be used in conjunction with the IS4000 (da Vinci Xi) Surgical Systems and a compatible Ethicon Endo - Surgery Generator and Hand Piece.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Nadine Nasr Regulatory Affairs Phone Number: 408-523-7093Fax Number: 408-523-8907 Email: Nadine.nasr@intusurg.com
Date Summary Prepared:	March 31, 2015
Trade Name:	IS4000 8 mm Harmonic ACE™ Curved Shears
Common Name:	System, Surgical, Computer Controlled Instrument (instrument, ultrasonic surgical)
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Codes:	NAY (System, Surgical, Computer Controlled Instrument)
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	*da Vinci* 8 mm Harmonic ACE™ device, cleared under K112584

Device Description

The IS4000 8 mm Harmonic ACE Curved Shears is a single-use, sterile instrument used to deliver ultrasonic energy to enable transection and coagulation of tissue. The movement and function of the IS4000 8 mm Harmonic ACE Curved Shears are controlled by the surgeon from the Surgeon Console of the *da Vinci Xi* Surgical System (model IS4000). The instrument is compatible with the Ethicon Hand Piece (model HP054) and Ethicon Endo-Surgery Generator (model G11).

Intended Use/Indications for Use:

The IS4000 8 mm Harmonic ACE™ Curved Shears is intended for soft tissue incisions when bleeding control and minimal thermal injury are desired. It is designed to be used in conjunction with the IS4000 (*da Vinci Xi*) Surgical System and a compatible Ethicon Endo-Surgery Generator and Hand Piece.

Technological Characteristics:

In terms of intended use, indications for use, and technological characteristics, the IS4000 8 mm Harmonic ACE Curved Shears are substantially equivalent to the currently marketed *da Vinci* 8 mm Harmonic ACE device, cleared under K112584.

Performance Data:

Performance test data (bench and animal tests) demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements for the IS4000 8 mm Harmonic ACE Curved Shears. The testing conducted consisted of design verification, reliability, and animal testing.

Design Verification:

The testing provided in this submission consisted of dimensional measurements, mechanical, and functional verification.

Test	Results
Design Verification – The purpose of this test was to verify that the instrument met the dimensional, mechanical, functional, and electrical requirements and specifications. Test methods were based on pre-defined test procedures, and objective pass/fail criteria were defined in the protocol and used. Sample sizes up to six units were used. The following design verification tests were performed: - Dimensional - Mechanical - Electrical - User/Equipment Interface - Cleaning and Sterilization - Packaging - Labeling	- All final tests PASSED

Reliability:

The testing provided in this submission consisted of simulated use cycling test articles through their typical use environment, including sterilization. The evaluation method included visual inspections as well as functional testing.

Test	Results
Design Verification, Life – The purpose of this test was to verify that the instrument was robust when exposed to a typical use environment. A sample size of six was used. Test articles were cycled through simulated clinical use, including the following: - Surgical Maneuvers and Tasks - Visual Inspection - Mechanical Stressing - Equipment Interface - RFID Functional Test	- All final tests PASSED

Animal Testing:

The testing provided in this submission was performed using simulated clinical models (animal) to confirm that the IS4000 8 mm Harmonic ACE Curved Shears meets the user needs and intended use.

Test	Summary
Design Validation – The purpose of this testing was to confirm that the IS4000 8 mm Harmonic ACE™ Curved Shears meets the user needs and intended use as documented in the Product Requirements document. Test methods were based on pre-defined test procedures and objective pass/fail criteria were defined in the protocol and used.	All final tests PASSED

Human Factors and Usability Testing:

After review of IS1200, IS2000, and IS3000 *da Vinci* Harmonic instruments data (e.g., field actions, MDRs, etc.), an analysis of predicate device comparison, and formative usability testing of the IS4000 Harmonic ACE instrument, it was concluded that the usability of the IS4000 Harmonic ACE instrument, when used by the intended users in the intended use environment in foreseeable use scenarios, is safe and effective.

Summary:

Based on the intended use, indications for use, technological characteristics, and the results of the verification and validation testing, the IS4000 8 mm Harmonic ACE Curved Shears meets all verification and validation requirements and is considered substantially equivalent to the predicate device.